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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,209	05/10/2001	Ulf Eriksson	1064/44740CP	3846

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,209	ERIKSSON ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,46-49,59 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *36,47 and 49* is/are allowed.

6)☒ Claim(s) *46,48,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 June 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/20/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 36, 46-49, 59 and 60 are pending and under consideration.

Applicants amendment of 7/16/2004 has overcome the following rejections/objections: The objection to Figure 19, the rejections under 35 U.S.C. §112, second paragraph, the rejection of claims 36, 47 and 49 under 35 U.S.C. §112, first paragraph for lack of adequate written description, , the rejection of claims 36, 46-49, 59 and 60 under 35 U.S.C. §112, first paragraph for lack of enablement of functional equivalents, analogs, or proteins with 85% identity to the disclosed sequences, and the rejection under 35 U.S.C. §102(a) over Ferrara et al.

New rejections apply.

Formal Matters:

The disclosure is objected to because of the following informalities. Appropriate correction is required for each item listed:

Figures 13, 14, 20, 26A-26V, 27A-F, 28A-F, 30A-D, 31A-D, 32A-D and 33A-D remain objected to because the photocopies submitted are of insufficient quality. No details can be discerned, for example there are numerous blots with no bands visible. It does not appear that legible copies were submitted with the specification as originally filed. If applicants wish to correct the figures, they must point out where basis is found in the specification as originally filed for the information newly conveyed, or in which application that may have been incorporated by reference such basis may be found.

Applicants traversal that the figures are legible is not persuasive. It may well be that the figures applicants have in their possession are legible, but the ones in the file at the USPTO are not.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59 and 60 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using human or murine PDGF-C or functional fragments thereof to treat a mammalian species, does not reasonably provide enablement for treatment of any and all birds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

With regard to the scope of treating birds, the specification has only described PDGF-C from "murine" and human species. It is noted that "murine" in this case is mouse; the term "murine", as used in the art, is generic to rats and mice. While it is predictable that other mammals will have PDGF-C homologs, it is not predictable that the disclosed human and mouse homologs would be active, and there is no guidance, direction or working example as to how to make species that would work in birds. The art recognizes that while animals often have homologous genes (i.e. evolutionarily related genes that encode proteins with similar function), the nature of changes in a single protein between species is in any way predictable, nor is it predictable that a homologous protein will have equivalent function in another species. For example, the art appreciates that birds often have proteins homologous to those found in other species, such as human, but which serve distinctly different functions in the avian species. For example, it is known in the art that exogenous growth hormone exerts a lipolytic effect in mammals, but a lipogenic effect in chickens (see L.A. Cogburn et al., Journal of Nutrition 119:1213 for example). Even within a species, closely related proteins can have divergent function the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities. For example, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth

muscle cells, which is opposite to the mitogenic activity of naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). The differences between PDGF and VEGF are also seen *in vivo*, wherein endothelial-pericyte associations in the eye are disrupted by intraocular administration of PDGF but accelerated by intraocular administration of VEGF (Benjamin et al., 1998, Development 125:1591-1598; see Abstract and pp. 1594-1596). Given the lack of description of PDGF-C from species other than mouse or human and especially the lack of any PDGF-C from any avian species, the lack of guidance, direction or working examples, and the state of the art being that it is unpredictable what the equivalent protein, if any, from other species would be or what function it would have, it would require undue experimentation to make PDGF-C within the metes and bounds of the claims that would be reasonably expected to have the desired effect in birds.

Applicants traversal in the paper filed 7/16/2004 has been fully considered but is not deemed persuasive. Applicants argue that "animal treatment data are usually transferable among different species." This argument has been fully considered but is not deemed persuasive because it is not supported by any facts or evidence pertinent to this case, but appears to merely be the opinion of the attorney or applicant.

Rejections Over Prior Art:

As stated in the previous Office Action, the truncated form of PDGF-C disclosed as being active in the instant specification consists of residues 230-345. The earliest disclosure of that species is found in provisional application 60/135,426, filed 5/21/1999. Accordingly, priority for Claims 46, 48, 59 and 60 is set at 5/21/1999.

Gao et al., U.S. Patent Number 6,528,050, disclosed the full-length and truncated forms of human PDGF-C, which they named ZVEGF3, in their earliest priority application, having filing date 12/7/1998. Accordingly, the art is applied:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46, 48, 59 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al., U.S. Patent Number 6,528,050.

Gao et al. discloses both full-length and truncated ZVEGF3. Methods of using the protein consistent with those claimed herein are disclosed. In particular, claim 46 corresponds to claim 1 of Gao et al. Gao discloses activation of the PDGF-α receptor and column 5, and such activation is further inherent to the method of Gao's claim 1. Also see column 38. Angiogenesis is also disclosed at column 38 as being inducible using the protein, including in the context of wound healing, which is the subject of Gao's claim 8. Accordingly, the claims are anticipated by Gao et al.

Advisory Information:

Claims 36, 47 and 49 are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed

copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner

9/30/2004